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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,358	10/02/2003	Karine Vidal	88265-6852	8288

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,358	VIDAL ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *12-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10 and 11* is/are rejected.

7)☒ Claim(s) *5 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed March 18, 2004 is acknowledged, in which a set of drawings (Figs. 1-7) have been submitted, and brief description of Figs. 6 and 7 have been added to page 4 of the specification.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-11 in the response filed September 7, 2004 is acknowledged. The traversal is on the ground(s) that claims directed to methods of use of a compound or composition may also be considered with a compound or composition claim provided that the method claims include all of the features of an allowable composition claim, thus when claim 1 is found to be patentable, dependent claims 12-16 should also be allowed since they will include all the features of allowable composition claim 1. The response has been considered, in the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. As indicated in the restriction requirement dated August 26, 2004, until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims has maintained.

Informalities

The disclosure is objected to because of the following informalities:

3. The specification recites amino acid and nucleotide sequences (e.g., Figs 6 and 7, page 10, lines 22 and 24; page 13, lines 3 and 5), but the sequence identifiers "SEQ ID NO:" of these sequences are not indicated. Appropriate correction is required.

4. Fig. 6 is objected to because the bold print for OPG sequence is not clearly indicated, it is not obvious which amino acid residue is the starting point for OPG; and Fig. 7 is objected to because the nucleotide and amino acid sequences of OPG are shown in two pages, thus, it should be labeled as Fig. 7A and 7B. Appropriate correction is required.

Claim Objections

5. Claim 3 is objected to because the claim recites "SEQ ID. No.1", which is not proper. Use of "SEQ ID NO:1" is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Simonet *et al.* (Cell 89, 309-319 (1997)).

Simonet *et al.* teach osteoprotegerin (OPG) is a secreted glycoprotein that regulates bone resorption and has 4 potential sites of N-linked glycosylation (page 310, left column; Fig 1B), OPG is synthesized as an approximately 55 kDa monomer within the cell and is converted to disulfide –linked dimer of approximately 110 kDa (the paragraph bridged pages 310 and 311), which is approximately 130 kDa (claims 1and 2) since the term "approximately" is not specifically defined in the specification. Claim 1 recites osteoprotegerin obtainable from human

or bovine milk, however, the claimed osteoprotegerin cannot be differentiated from the osteoprotegerin in the reference since there is no characteristic of the protein indicated in the claim.

7. Claims 1, 3, 6-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Simonet *et al.* (WO 99/53942, published October 28, 1999).

Simonet *et al.* teach a composition comprising osteoprotegerin (OPG) is useful for treating or preventing cardiovascular disease (page 4, lines 25-35), where human OPG has an amino acid sequence of SEQ ID NO: 2 (401 amino acid residues, including N-terminal leader sequence of 21 amino acids; page 6, line 33-page 7, line 15; claims 1 and 3), which has 100% sequence identity to the claimed SEQ ID NO:1 (see attached sequence match); and OPG pharmaceutical compositions include a therapeutically effective amount of OPG in admixture with one or more pharmaceutically acceptable formulation materials, e.g., water, and physiological saline solution, once the therapeutic composition has been formulated, it may be stored as a solution, suspension, solid or dehydrated or lyophilized powder (pages 20, line 32-page 21, line 32; claims 6-8 and 10). Although claim 1 recites osteoprotegerin obtainable from human or bovine milk, the claimed osteoprotegerin is not different from the osteoprotegerin in the reference since there is no characteristic of the protein indicated in the claim. Since the pharmaceutical composition of Simonet *et al.* contains a therapeutically effective amount of OPG, it would be expected that the amount of OPG is effective to assist in formation of lymphoid tissues and regulation of immune responses in a subject, which meet the criteria of the claimed pharmaceutical composition.

8. Claims 1, 3, 4, 6-8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyle *et al.* (U.S. Patent 6,015,938, January 18, 2000).

Boyle *et al.* teach an osteoprotegerin (OPG) obtained by expressing in host cells is useful for treating bone disease (column 2, lines 23-53), where human OPG has an amino acid sequence of SEQ ID NO: 6 (401 amino acid residues, including N-terminal leader sequence of 21 amino acids; column 7, lines 40-65; claims 1 and 3), which has 100% sequence identity to the claimed SEQ ID NO:1 (see attached sequence match); and a pharmaceutical composition comprising a therapeutically effective amount of OPG together with a pharmaceutically acceptable diluent, carrier, solubilizer, emulsifier, preservative and/or adjuvant, the composition may be in a liquid or lyophilized form and comprises a diluent (e.g., phosphate buffer) and carrier (e.g., human serum albumin or gelatin; column 9, lines 20-45; claims 6-8 and 10), and the composition containing OPG with a carrier (e.g. gelatin) may be administered by oral (column 9, lines 46-51; claims 4 and 11). Although claim 1 recites osteoprotegerin obtainable from human or bovine milk, the claimed osteoprotegerin is not different from the osteoprotegerin in the reference since there is no characteristic of the protein indicated in the claim. Since the pharmaceutical composition of Boyle *et al.* contains a therapeutically effective amount of OPG, it would be expected that the amount of OPG is effective to assist in formation of lymphoid tissues and regulation of immune responses in a subject, which meet the criteria of the claimed pharmaceutical composition.

Claim Objections

7. Claims 5 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Claims 1-4, 6-8 and 10-11 are rejected, and claims 5 and 9 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
November 20, 2004